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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,494	10/07/2003	Lawrence J. Mulligan	P-11354.00	5535

27581 7590 01/27/2006

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EXAMINER
GREENE, DANA D

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/680,494	**Applicant(s)** MULLIGAN ET AL.	
	Examiner Dana D. Greene	**Art Unit** 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 7, 9-12, 15, 16, and 18-21 stand rejected under 35 U.S.C. §102(b) as being anticipated by Bennett et al. (US 5,214,098, hereinafter "Bennett"). Bennett is considered to disclose:

setting a test ESI for delivery of an ESS therapy (*see* col. 14, ln. 8-15, Bennett). The disclosed use of a test mode is considered to anticipate the claimed method of setting a test ESI because both allow sampling to identify the effective coupling intervals for subsequent clinical use;

applying the ESS therapy at the test ESI (*see* col. 14, ln. 10-36, Bennett). This reference teaches a ventricular EGM that may be detected by a sense amplifier and telemetered out as paired or coupled atrial stimulation is commanded in a temporary test mode so that the pacemaker or therapy may be delivered with certain test intervals;

determining a potentiation ratio (PR) and a recirculation fraction (RF) (*see* col. 2, ln. 1-10, Bennett). Bennett teaches the continuous performance of contractile force effect and removal, which cause the effect to decay resulting in the recirculation fraction;

storing the previously determined PR and RF with the test ESI (*see* col. 14, ln. 15-27, Bennett). Bennett is considered to anticipate the claimed method of storing the PR and RF because both work with an ESI resulting in a maximum optimization/monitoring parameter, preferably computed as the product of PR and RF, is determined as the optimal ESI. The operating ESI may be automatically adjusted, and/or PR and RF data may be stored for monitoring purposes;

incrementing or decrementing the test ESI to a new value test ESI within a predetermined range of values and repeating the first four steps, wherein the new value test ESI is substituted for the test ESI (*see* col. 18, ln. 33-42, Bennett). Bennett is considered to anticipate the claimed method of incrementing or decrementing the test ESI because both teach a coupling interval that is adjustable and can be shortened by one increment;

calculating a product of RF and PR for each test ESI (*see* col. 14, ln. 15-27, Bennett). Bennett is considered to anticipate the claimed method of storing the PR and RF because both work with an ESI resulting in a maximum optimization/monitoring parameter, preferably computed as the product of PR and RF, is determined as the optimal ESI. The operating ESI may be automatically adjusted, and/or PR and RF data may be stored for monitoring purposes;

determining an optimal ESI that corresponds to a maximal product of RF and PR and setting an operating ESI to the optimal ESI (*see* col. 14, ln. 15-36, Bennett). The disclosed method of detection is considered to anticipate the claimed method of determining an optimal ESI because both work such that as the ESI is shortened, a maximal effect is reached when the ESI is slightly longer than the physiological refractory period. Further, an electrical depolarization occurs without a mechanical contraction or with a substantially weakened contraction.

Referring to claims 2, 9, 11, and 18 Bennett is considered to disclose a method, wherein the ESS therapy delivery is performed in an implantable pulse generator (*see* col. 14, ln. 49-59, Bennett). The disclosed implantable device is considered to anticipate the claimed implantable pulse generator because both are cardiac stimulation devices and delivering extra-systolic stimulation to achieve post-extra-systolic potentiation in the treatment of cardiac mechanical insufficiency. In this connection, the device measures potentiation ratio and recirculation fraction for use in optimizing and assessing the response to extra-systolic stimulation.

With reference to claims 3, 6, 7, 12, 15, and 16, Bennett is considered to disclose a method wherein the PR and RF is determined upon a contractile function derived from an output signal from a mechanical sensor (*see* col. 2, ln. 47-55, Bennett). The disclosed contractile force is considered to anticipate the claimed determination made upon a contractile function because both work with optimization/monitoring parameters calculated as a function of potentiation ratio, PR, and recirculation fraction, RF, derived from measurements of myocardial contractile function during and after ESS.

Referring to claims 10 and 20, Bennett is considered to disclose:

determining a baseline contractile function parameter when an ESS therapy is withheld or not delivered for a sufficient time or number of cardiac cycles for any related hemodynamic enhancement to substantially cease (*see* col. 2, ln. 1-10, Bennett);

delivering the ESS therapy for an interval of time or for a number of cardiac cycles; calculating an ESS therapy contractile function parameter during the delivery of the ESS therapy (*see* col. 14, ln. 10-36, Bennett). This reference teaches a ventricular EGM that may be detected by a sense amplifier and telemetered out as paired or coupled atrial stimulation is commanded in a temporary test mode so that the pacemaker or therapy may be delivered with certain test intervals;

calculating a potentiation ratio based on the baseline contractile function parameter and the SS therapy contractile function parameter (*see* col. 2, ln. 1-10, Bennett). Bennett teaches the continuous performance of contractile force effect and removal, which cause the effect to decay resulting in the recirculation fraction;

ceasing delivery of the ESS therapy and determining a recirculation fraction for several cardiac cycles following the ceasing delivery of the ESS therapy (*see* col. 14, ln. 15-27, Bennett). Bennett is considered to anticipate the claimed method of storing the PR and RF because both work with an ESI resulting in a maximum optimization/monitoring parameter, preferably computed as the product of PR and RF, is determined as the optimal ESI. The operating ESI may be automatically adjusted, and/or PR and RF data may be stored for monitoring purposes.

Referring to claim 19, Bennett is considered to disclose:

a method wherein the PR and RF is determined upon a contractile function derived from an output signal from a physiologic sensor, said physiologic sensor comprising a one of: a saturated oxygen sensor, a lactate sensor, a glucose sensor (*see* col. 7, ln. 25-35, Bennett). The disclosed oxygen saturation sensor is considered to anticipate the claimed sensors because they may all be usefully employed for deriving a contractile function metric.

With reference to claim 21, Bennett is considered to disclose:

means for setting a test ESI (*see* col. 14, ln. 8-15, Bennett). The disclosed use of a test mode is considered to anticipate the claimed method of setting a test ESI because both allow sampling to identify the effective coupling intervals for subsequent clinical use;

means for determining a potentiation ratio (PR) and a recirculation fraction (RF) (*see* col. 2, ln. 1-10, Bennett). Bennett teaches the continuous performance of contractile force effect and removal, which cause the effect to decay resulting in the recirculation fraction;

means for storing the previously determined PR and RF with the test ESI (*see* col. 14, ln. 15-27, Bennett). Bennett is considered to anticipate the claimed method of storing the PR and RF because both work with an ESI resulting in a maximum optimization/monitoring parameter, preferably computed as the product of PR and RF, is determined as the optimal ESI. The operating ESI may be automatically adjusted, and/or PR and RF data may be stored for monitoring purposes;

means for incrementing or decrementing the test ESI to a new value within a predetermined range of values and repeating the first three steps (*see* col. 18, ln. 33-42, Bennett). Bennett is considered to anticipate the claimed method of incrementing or decrementing the test ESI because both teach a coupling interval that is adjustable and can be shortened by one increment;

means for calculating a dot product of RF and PR for each test ESI (*see* col. 14, ln. 15-27, Bennett). Bennett is considered to anticipate the claimed method of storing the PR and RF because both work with an ESI resulting in a maximum optimization/monitoring parameter, preferably computed as the product of PR and RF, is determined as the optimal ESI. The operating ESI may be automatically adjusted, and/or PR and RF data may be stored for monitoring purposes;

means for determining an optimal ESI that corresponds to a maximal product of RF and PR; and means for setting an operating ESI to the optimal ESI (*see* col. 14, ln. 15-36, Bennett). The disclosed method of detection is considered to anticipate the claimed method of determining an optimal ESI because both work such that as the ESI is shortened, a maximal effect is reached when the ESI is slightly longer than the physiological refractory period. Further, an electrical depolarization occurs without a mechanical contraction or with a substantially weakened contraction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 5, 8, 13, 14, and 17 stand rejected under 35 U.S.C. as being unpatentable over Bennett in view of Mulligan et al. (US 6,438,408 B1, hereinafter "Mulligan"). Bennett is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed accelerometer. However, Mulligan teaches the use of an accelerometer (*see* col. 21, ln. 15-25, Mulligan). It would have been obvious to one of ordinary skill in the art to combine the teachings of Bennett with the accelerometer of Mulligan for the purpose of sensing a parameter relating to RV contractile function.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana D. Greene

Dana D. Greene

George Manuel
Primary Examiner